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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,829	Applicant(s) KRIVITSKI ET AL.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008 and 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species A (claims 14 and 16-20) in the reply filed on 7/18/2008 is acknowledged.

Response to Arguments

2. Applicant's arguments with respect to claims 14 and 16-20 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "(a) passing a guide wire through an indicator lumen in an elongate catheter body to pass a portion of the guide wire through a terminal port of the indicator lumen; (b) passing the indicator through the lumen to pass from the elongate catheter body through the terminal port" must be shown or the feature(s) canceled from the claim(s). Note that Fig. 17 depicts the guidewire closing off the terminal port and no flow through the terminal port and Fig. 12 depicts flow from both terminal and injection ports but does not depict a guide wire. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

Art Unit: 3736

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for estimating the distribution of the injected volume V in the particular catheter construction (see specification [00142]) and for calculating the equation $Q=k(T_b-T_i)*V(1-a)/S$, does not reasonably provide enablement for “compensating for a volume of the indicator passing through the terminal port

Art Unit: 3736

corresponding to the relationship $Q=k(T_b-T_i)*V(1-a)/S$ ". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The equation detailed in claim 20 is listed as "Equation 26" in [00142] in the specification. However, no detail regarding its use with respect to "compensating" are apparent. It is unclear how one of ordinary skill in the art would use this equation for "compensating" as required by claim 20, particularly as it is unclear what is meant by "compensating for passage of the indicator through the terminal port" in the context of the claim language and relevant portions of the specification. Furthermore, no active language detailing or suggesting how the equation is applied is present.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 20 lines 1-4 include the limitation "wherein compensating for passage of the indicator through the terminal port includes compensating for a volume of the indicator passing through the terminal port corresponding to the relationship $Q=k(T_b-T_i)*V(1-a)/S$ ". It is unclear from the claim what exactly is "corresponding to the relationship." For example, it appears "compensating for a volume of the indicator" could be "corresponding to the relationship." Alternatively, it appears "a volume of

Art Unit: 3736

indicator passing through the terminal port” could be “corresponding to the relationship.”

It also seems possible that neither of these is the intended meaning of the claim, and if this is the case it is unclear exactly what is meant by the above cited limitation(s). Line 4 recites the limitation “the relationship.” This limitation lacks antecedent basis. Lines 5 and 6 recite the limitation “the temperature.” These limitations lack antecedent basis in the claims. Line 7 recites the limitation “the volume.” This limitation lacks antecedent basis in the claims. Line 8 recites the limitations “the area,” “the temperature versus time curve,” and “the mixing.” These limitations lack antecedent basis in the claims. Line 9 recites the limitation “the portion.” This limitation lacks antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 14 and 16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,224,585 to Pfeiffer (“Pfeiffer”).

11. Pfeiffer teaches:

In reference to Claim 14

A method of introducing an indicator through a catheter (1), the method comprising: (a) passing a guide wire (10) through an indicator lumen (8, 2, and all connected hollow interior portions) in an elongate catheter body to pass a portion of the guide wire through a terminal port (distal tip of 1, see Fig. 2) of the indicator lumen; (b) passing the indicator ("heparinized solution" is an indicator of some sort, for example, the presence of heparin in blood drawn downstream of the injection area would indicate blood flow, etc.) through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (9) intermediate the terminal port and a proximal end of the catheter body (see col. 6 lines 9-20, note that the solution is continually applied, and that because the distal lumens of 1 are all interconnected at least some of the solution would exit all of the distal apertures); and (c) compensating for passage of the indicator through the terminal port (by continually applying the solution, the indicator which passes through the various ports would be compensated for in the sense that it is replaced by new solution).

In reference to Claim 16

The method of claim 14 (see above) further comprising passing the guide wire through a reduced cross sectional area of the indicator lumen (note that the lumen at 3 has a greater cross sectional area than at 8).

In reference to Claim 17

The method of claim 14 (see above) further comprising passing the indicator through the indicator lumen to contact a portion of the guide wire (when solution is injected, it would contact the guidewire).

In reference to Claim 18

The method of claim 14, further comprising passing the guide wire through a reduced cross sectional area of the indicator lumen to increase a flow of the indicator through the injection port (because the guidewire decreases the area for flow to occur, it would inherently increase the flow relative to a configuration with no guidewire present)

In reference to Claim 19

The method of claim 14 (see above) wherein compensating for passage of the indicator through the terminal port includes compensating for a volume of the indicator passing through the terminal port (volume that exits is compensated for, i.e. replaced, by the continual application of solution).

In reference to Claim 20

The method of claim 14, wherein compensating for the passage of the indicator through the terminal port includes compensating for a volume of the indicator passing through the terminal port corresponding to the relationship $Q=k(T_b-T_i)*V(1-a)/S$ (note that the volume passing from the various distal ports of Pfeiffer would “correspond to the relationship” in the sense that the relationship models the physical occurrence of fluid of some temperature flowing through multiple exit ports into another flowing fluid), where Q is a blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator, T_b is the temperature of the measured flow prior to injection, T_i is the temperature of the indicator prior to entering the measured flow, V is the volume of the indicator, S is the area under the temperature versus time curve resulting from the mixing of the indicator and a is the portion of the indicator passing through the terminal

Art Unit: 3736

port (note that all of these values would exist for the method of Pfeiffer whether they were actively collected or not).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 10/28/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736